

REMARKS

The requirement to elect species is once again traversed, because an additional species III has been added in the Office Action.

Previously, two species had been identified, and Species I had been elected. (Office Action, August 11, 2004 and Election, August 17, 2004). Species I and II are directed to different embodiments of a claimed auger or piercing member. In Species I, the auger or piercing member includes a conical spike; in Species II, the auger or piercing member includes a fluted, screw-like element.

Now, for the first time, a Species III has been identified, where the alleged Species III is Figures 11-12. Figure 11 is "a cutaway view of an integrated anastomosis tool, where the tool is in an initial state," and Figure 12 is "a cutaway view of the tool of FIG. 11 in a deployed state." (Specification, page 6, lines 16-18). Figures 1-2 and 4-5 are merely two different embodiments of the distal end of the tool of Figures 11-12. (e.g., Specification, page 5, line 24 through page 6, line 1; page 6, lines 4-6, 24-25 ("The cutter 4 and auger 6 may be part of an integrated anastomosis tool")). Thus, Species III is not a proper species, because the relationship between it and each of Species I and II is clear; it is not and cannot be independent of either or both of Species I and II. The Office Action implicitly admits this by failing to provide any rationale or basis in fact or law whatsoever for the identification of a new Species III.

Indeed, the identification of a new Species III without any rationale for doing so is improper. Under the Administrative Procedure Act (5 U.S.C. § 706) federal administrative agencies such as the Patent and Trademark Office must support their decisions with substantial evidence for those decisions to be valid:

A reviewing court reviews an agency's reasoning to determine whether it is "arbitrary" or "capricious," or, if bound up with a record-based factual conclusion, to determine whether it is

supported by "substantial evidence." (*Dickinson v. Zurko*, 1999 U.S. Lexis 4004, \*24; 527 U.S. 150 (1999) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 89-93(1943)).)

By providing no evidence or rationale at all for the identification of a new Species III, necessarily there is no "substantial evidence" as required by law, and the identification of Species III and the corresponding restriction requirement are invalid as a matter of law.

Further, the addition of a new species and the requirement to elect from a new assortment of species is objected to under MPEP 811.02. An additional restriction requirement "may be made when it becomes proper." (MPEP 811.02). However, nothing has changed since the previous election to make it "become[] proper" to identify a new species.

Consequently, it is requested that the Examiner withdraw the newly-alleged Species III from the restriction requirement. If the restriction requirement is withdrawn with regard to Species III, the traverse of the restriction requirement between Species I and II will be withdrawn.

Should the restriction requirement be withdrawn with regard to Species III, while being maintained as to Species I and II, acknowledgement that claim 17 is generic is requested. The Office Action identifies claim 1 as generic. Claim 17 is also generic, because the claimed "auger" can be the conical spike of Species I or the fluted, screw-like element of Species II.

Having traversed the restriction requirement, the previous election of Species I is reiterated. Claims 1-15 and 17-51 read on elected Species I.

**REQUEST FOR ALLOWANCE**

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



Brian A. Schar  
Attorney for Cardica, Inc.  
Reg. No. 45,076  
Tel. No. (650) 331-7162